

REMARKS

In the Final Office Action dated June 13, 2008, the Examiner rejected claims 1-4, 6-12, 18, 19, 21-26, 27-29, 31, and 34 under U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,053,003 to Dadson et al. ("Dadson") in view of U.S. Patent No. 4,999,885 to Lee ("Lee"); rejected claims 5, 13, 15-17, 20, and 30-33 under U.S.C. § 103(a) as being unpatentable over Dadson in view of Lee, and further in view of U.S. Patent No. 5,820,582 to Keilman ("Keilman"); rejected claim 14 under U.S.C. § 103(a) as being unpatentable over Dadson in view of Lee, and further in view of U.S. Patent No. 4,772,497 to Maasola ("Maasola"); and rejected claim 35 under U.S.C. § 103(a) as being unpatentable over Dadson in view of Lee, and further in view of U.S. Patent Application No. 2002/0115795 to Shang et al. ("Shang").

By this Reply, Applicant has amended claims 1-6, 8-10, 12, 13, 15, 18, 19, 21, and 23-32. Accordingly, claims 1-35 are currently pending in this application. No new matter has been added by this Reply.

Independent Claim 1 has been amended to recite, among other things, that "the package includes a non-sterile line set, which includes a non-sterile first tubular line element, a second non-sterile tubular line element and at least one non-sterile component connected to the first and second non-sterile tubular line elements." (Emphasis added.) Claim 1 has also been amended to recite that the "package compris[es] organizing means configured to organize the line set within the package such that no part of the line set extends across another part of the line set during sterilization of the package, wherein the package including the non-sterile line set is configured to substantially eliminate any risk of damage to the package or line set during sterilization." (Emphasis added.) Independent method claim 27 has been

amended to include similar elements. Support for these claim amendments can be found in the specification, for example, at page 1, line 16 - page 2, line 20 and at page 2, line 35 - page 3, line 20.

REJECTION UNDER § 103(a)

In the Office Action, the Examiner rejected claims 1-4, 6-12, 18, 19, 21-26, 27-29, 31, and 34 under U.S.C. § 103(a) as being unpatentable over Dadson in view of Lee, rejected claims 5, 13, 15-17, 20, and 30-33 under U.S.C. § 103(a) as being unpatentable over Dadson in view of Lee and Keilman, rejected claim 14 under U.S.C. § 103(a) as being unpatentable over Dadson in view of Lee and Massola, and rejected claim 35 under U.S.C. § 103(a) as being unpatentable over Dadson in view of Lee and Shang. Applicant traverses these rejections.

Several basic factual inquiries must be made in order to determine the obviousness or non-obviousness of claims of a patent application under 35 U.S.C. § 103. These factual inquiries, set forth in Graham v. John Deere Co., 383 U.S. 1, 17, 148 U.S.P.Q. 459, 467 (1966), require the Examiner to:

- (1) Determine the scope and content of the prior art;
- (2) Ascertain the differences between the prior art and the claims in issue;
- (3) Resolve the level of ordinary skill in the pertinent art; and
- (4) Evaluate evidence of secondary considerations.

The obviousness or non-obviousness of the claimed invention is then evaluated in view of the results of these inquiries. Graham, 383 U.S. at 17-18, 148 U.S.P.Q. at 467; see also KSR Int'l Co. v. Teleflex Inc., 82 U.S.P.Q.2d 1385 (U.S. 2007); see also M.P.E.P. § 2141(II).

Applicant traverses the Examiner's rejection of claims 1-4, 6-12, 18, 19, 21-26, 27-29, 31, and 34 under 35 U.S.C. § 103(a) as being unpatentable over Dadson in view of Lee at least because the Examiner has not properly determined the scope and content of the prior art and the cited references do not disclose every limitation of the amended independent claims 1 and 27, for example. In fact, the differences between the cited references and amended claims 1 and 27 are quite significant.

The Examiner contends that Dadson discloses "a package [that] includes a line set which comprises a first tubular line element 54, a second tubular line element 52, and elements 60, 61, 65, 69 connected to the tubular line elements 54 and 52 (See. Fig. 1)." (Office Action at 2.) The Examiner also cites to col. 5, lines 61-62 of Dadson, which further discloses that "[o]ne form of this invention is constituted by a package which contains the "Y" set." (Office Action at 14.) Moreover, the Examiner alleges that Lee teaches "to use an organizing means arranged to organize the line set such that no part of the line set extends across another part of the line set." (Office Action at 3.) Applicant disagrees with the Examiner's characterizations of Dadson and Lee. In particular, Applicant points out that Fig. 1 of Dadson does not depict a package, but instead, merely depicts a line set. And, despite the use of the word "package" in column 5 of Dadson, Dadson does not disclose any details of a "package," nor is any disclosure provided regarding how various elements of a line set are configured within the "package." In addition, contrary to the Examiners assertions, Lee does not teach "organizing means configured to organize the line set such that no part of the line set extends across another part of the line set" as recited in independent claim 1. For example, Lee discloses a clip that may be used at a bed side of a patient in a hospital.

(see col. 1.) The clip is adapted to organize separate tubings from various sources and various destinations around and on the patient. (Col. 1 and col. 2, lines. 47-49.) Thus, the separate tubings are not connected to each other and included in a “line set,” as recited in claim 1. Moreover, the clip disclosed in Lee is not configured to keep the flexible tubings from extending across each other at a distance from the clip. Nor is the clip of Lee configured to be used in “a package,” as recited in claim 1.

Nevertheless, in order to further the prosecution of this application, Applicant has amended independent claims 1 and 27 to recited additional elements that further overcome the cited references. In particular, Dadson does not disclose a “package [that] includes a non-sterile line set, which includes a non-sterile first tubular line element, a second non-sterile tubular line element and at least one non-sterile component connected to the first and second non-sterile tubular line elements” (emphasis added), as recited in amended independent claims 1 and 27. In fact, Dadson teaches away from a package containing a non-sterile line set. Dadson discloses that the “invention is constituted by a package which contains the ‘Y’ set shown in FIG. 1, the item shown in FIG. 2, and optionally the item shown in FIG. 3. All of these are supplied in sterile condition in a single PD package.” (Col. 5, lines 61-65.) Thus, Dadson does not disclose a package containing a non-sterile line set.

Similarly, Dadson fails to disclose “organizing means configured to organize the line set within the package such that no part of the line set extends across another part of the line set during sterilization of the package, wherein the package including the non-sterile line set is configured to substantially eliminate any risk of damage to the package or line set during sterilization.” (emphasis added), as recited in amended

independent claim 1 (a corresponding method step being recited in amended claim 27).

The sterilization of the line set elements in Dadson is completed prior to these elements being placed in a “package,” and thus, Dadson does not disclose a package configured to withstand sterilization. Nor does Dadson disclose a “package” comprising organizing means configured to organize the line set within the package to substantially eliminate any risk of damage to the package or line set during sterilization. Lee similarly does not disclose a package including a non-sterile line set configured to undergo sterilization, the non-sterile line set being organized within the package to substantially eliminate the risk of damage to the package or line set during sterilization, as required by amended independent claims 1 and 27. Accordingly, Lee also fails to overcome the above-mentioned deficiencies of Dadson.

For at least the reasons discussed above, independent claims 1 and 27 are allowable over Dadson and Lee and Applicant respectfully asks the Examiner to withdraw the § 103(a) rejection of these claims. Accordingly, claims 2-4, 6-12, 18, 19, 21-26, 28, 29, 31, and 34 are allowable at least due to their dependence from allowable amended independent claim 1 or 27 and due to their additional recitations of novel subject matter. Thus, Applicants respectfully request that the § 103(a) rejection of these claims be withdrawn as well.

The Examiner rejected claims 5, 13, 15-17, 20, and 30-33 under 35 U.S.C. § 103(a) as being unpatentable over Dadson in view of Lee and Keilman. Dadson, Lee, and Keilman do not disclose or suggest each and every limitation of the rejected claims. The Examiner contends that Keilman teaches “tubular line elements [that] are pre-shaped to extend along a desired path” and “tubular line elements . . . manufactured of

PVC,” among other things. (Office Action at 15-16.) Keilman does not, however, overcome the above-mentioned deficiencies of Dadson and Lee. Accordingly, claims 5, 13, 15-17, 20, and 30-33 are allowable at least due to their dependence from allowable amended independent claim 1 or 27 and due to their additional recitations of novel subject matter. Thus, Applicants respectfully request that the § 103(a) rejection of these claims be withdrawn.

The Examiner rejected claim 14 under U.S.C. § 103(a) as being unpatentable over Dadson in view of Lee and Massola. Dadson, Lee, and Massola do not disclose or suggest each and every limitation of the rejected claim. The Examiner contends that Massola teaches “the bag for medical solutions made of a mixture of polyolefin and an elastomer.” (Office Action at 19.) Massola does not, however, overcome the above-mentioned deficiencies of Dadson and Lee. Accordingly, claim 14 is allowable at least due to its dependence from allowable amended independent claim 1 and due to its additional recitations of novel subject matter. Thus, Applicant respectfully requests that the § 103(a) rejection of this claims be withdrawn.

The Examiner rejected claim 35 under U.S.C. § 103(a) as being unpatentable over Dadson in view of Lee and Shang. Dadson, Lee, and Shang do not disclose or suggest each and every limitation of the rejected claim. The Examiner contends that Shang teaches “the step of placing (exposing) the tube set in a steam autoclave.” (Office Action at 20.) Applicant disagrees with the Examiner’s characterization of Shang. Shang discloses materials that may be used to make medical devices that can withstand being placed through a steam autoclave. Shang does not , however, disclose a “package [that] includes a non-sterile line set, which includes a non-sterile first tubular

line element, a second non-sterile tubular line element and at least one non-sterile component connected to the first and second non-sterile tubular line elements” (emphasis added), as recited in amended independent claim 27. Nor does Shang disclose “the step of organizing the non-sterile line set within the package such that no part of the line set extends across another part of the line set during sterilization of the package, wherein the package including the non-sterile line set is configured to substantially eliminate any risk of damage to the package or line set during sterilization” (emphasis added), as recited in amended independent claim 27. Accordingly, Shang fails to overcome the deficiencies of Dadson and Lee. Thus, claim 35 is allowable over the cited references at least due to its dependence from allowable independent claim 27. Applicant respectfully asks the Examiner to withdraw the rejection of claim 35.

CONCLUSION

In view of the above amendments, Applicant asserts that the entire application is now in condition for allowance. A timely notice of allowance is earnestly requested.

The Examiner is invited to telephone the undersigned at (202) 408-4387, should the Examiner foresee any impediment to allowance.


The Office Action may contain statements or characterizations with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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